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02

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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09/546,201 04/10/00 POLO

J 930049.464/1

EXAMINER

HM22/0307

CHIRON CORPORATION
INTELLECTUAL PROPERTY - R440
P.O. BOX 8097
EMERYVILLE CA 94662-8097

FOLEY, S	
ART UNIT	PAPER NUMBER

1648
DATE MAILED:

9
03/07/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.

09/546,201

Applicant(s)

POLO ET AL.

Examiner

Shanon A. Foley

Art Unit

1648

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-45 is/are pending in the application.
- 4a) Of the above claim(s) 1-25, 27, and 45 is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 26 and 28-44 is/are rejected.
- 7) ☒ Claim(s) 34 is/are objected to.
- 8) ☐ Claims ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are objected to by the Examiner.
- 11) ☐ The proposed drawing correction filed on ____ is: a) ☐ approved b) ☐ disapproved.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

- 15) ☒ Notice of References Cited (PTO-892)
- 16) ☒ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 17) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 5.

- 18) ☐ Interview Summary (PTO-413) Paper No(s). ____.
- 19) ☐ Notice of Informal Patent Application (PTO-152)
- 20) ☐ Other: _____

DETAILED ACTION

Election/Restriction

Applicant's election without traverse of Group VIII in Paper No. 7 is acknowledged. Claims 1-45 are pending. Claims 1-25, and 27 are withdrawn from consideration. Claims 26 and 28-44 are examined to the extent that they read upon the elected invention.

Claim Objections

Claim 34 objected to because of the following informalities: "anyone" is presumed to mean "any one". Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 31 and 32 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 31 is drawn to a pathogenic agent that is a tumor. Tumors are not pathogenic agents. However, there are pathogenic agents, i.e. viruses, which are linked to tumor progression. The claim is presumed to be directed to tumor antigens.

Claim 32 is drawn to an additional pol II promoter. Is the additional pol II promoter referring to the second promoter in the expression cassette of claim 26, or is the additional pol II promoter a third promoter in the expression cassette?

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

Claims 26, 28, 29, 32-35, 41, 43, and 44 are rejected under 35 U.S.C. 102(a) as being clearly anticipated by Polo et al.

The claims are drawn to an expression cassette comprising a first promoter that forms double stranded RNA in vivo and a second promoter that encodes an antigen from viral antigens, such as HSV. The second promoter is a pol II promoter. The expression cassette is in a recombinant alphavirus and is a eukaryotic layered vector system.

Polo et al. teaches self-replicating viral RNA expression vectors within a RNA polymerase expression II cassette, CMV (see the first paragraph of the third column on page 518), that are derived from alphavirus DNA vectors that can be launched in vivo, see Figure 1. The expression of heterologous antigens is expressed at high levels from a self-replicating alphavirus vector transcribed in vivo, see the paragraph bridging columns 2 and 3 on page 517. Polo et al. teaches that a Sindbis virus-based vaccine were used to express HSV-1 glycoprotein B and was able to effectively stimulate protection against virus challenge, see the second paragraph on page 517. The teachings of Polo et al. clearly anticipate claims 26, 28, 29, 32-35, 41, 43, and 44.

Claim Rejections - 35 USC § 103

Claims 30, 31, 36-40, and 42 are rejected under 35 U.S.C. 103(a) as being unpatentable over Polo et al. as applied to claims 26, 28, 29, 32-35, 41, 43, and 44 above, and further in view of Dubensky et al. in US 6,015,686.

The claims are drawn to an expression cassette expressing a tumor antigen and/or a pathogenic agent from a bacteria, parasite, or fungus in delivery vehicles such as retrovirus, herpesvirus, poxvirus, adenovirus, parvovirus, and polyomavirus.

See the teachings of Polo et al. above. Polo et al. does not teach an expression cassette expressing a tumor antigen and/or a pathogenic agent from a bacteria, parasite, or fungus in delivery vehicles such as retrovirus, herpesvirus, poxvirus, adenovirus, parvovirus, and polyomavirus. However, Dubensky et al. does.

Dubensky et al. teaches a eukaryotic layered vector initiation cassette that expresses a heterologous sequence from RSV, HPV, HBV, HCV, EBV, HIV, HSV, FeLV, FIV, Hantavirus, HTLV I, HTLV II, and CMV, see claim 9 and column 4, lines 36-46. Dubensky et al. also teaches that the vector can utilize any of the promoters listed in claim 33, see column 4, lines 8-12. In addition, the vector can also direct the expression of bacterial, fungal, and parasitic antigens, see column 28, lines 4-19, and/or be anti-cancer related, see column 27, line 60 to column 28, line 2. Dubensky et al. also teaches that a wide variety of vectors can be utilized as the first layer of the vector initiation system, such as retrovirus, herpesvirus, and poxvirus, see column 32, lines 26-68.

One of ordinary skill in the art at the time the invention was made would have used any antigen of interest to express in any conventional recombinant vector claimed taught by

Art Unit: 1648

Dubensky et al. in the layered vector system taught by Polo et al. One of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention because both references teach a layered vector system and Dubensky et al. teaches how versatile the layered vector system is in using heterologous genes, promoters, and vectors. Therefore, due to the teachings of the references, the invention as a whole would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made, absent unexpected results.

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Berglund et al. 1998. Enhancing immune responses using suicidal DNA vaccines. Nature Biotechnology. Vol. 16, pages 562-565.

Leitner et al. 2000. Enhancement of tumor-specific immune response with plasmid DNA replicon vectors. Cancer Research. Vol. 60, pages 51-55.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shanon A. Foley whose telephone number is (703) 308-3983. The examiner can normally be reached on 7:30-4:30 M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel can be reached on (703) 308-4027. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-4242 for regular communications and (703) 308-4426 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Application/Control Number: 09/546,201

Page 6

Art Unit: 1648

Shanon Foley
March 3, 2001



**MARY E. MOSHER
PRIMARY EXAMINER
GROUP 1800**

1600